UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,172	03/21/2007	Hirotoshi Adachi	MUR-047-USA-PCT	4754

27955 7590 12/29/2010

TOWNSEND & BANTA
c/o PORTFOLIO IP
PO BOX 52050
MINNEAPOLIS, MN 55402

EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
12/29/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/584,172	ADACHI ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *4-8, 15, 16, 19, 20, 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,9-14,17,18,21 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/18/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' election filed 10/28/2010, and IDS filed 08/18/2006.

Claims 1-23 are pending.

Election/Restrictions

1. Applicant's election of invention I and species C, claims 1-3, 9-14, 17-18, 21, 23 in the reply filed on 10/28/2010 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 4-8, 15, 16, 19, 20, 22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim.

Claims 1-3, 9-14, 17-18, 21, 23 are included in the prosecution.

Specification

3. The abstract of the disclosure is objected to because it is more than one paragraph. Correction is required. See MPEP § 608.01(b).

4. 35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are: no spaces between words almost over the entire specification and this makes the disclosure unclear.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-3, 9-14, 17-18, 21, 23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 12/087,055. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the referenced copending applications and would be covered by any patent granted on the copending applications since the referenced copending applications and the instant application are claiming common subject matter as follows: transdermal device comprising holder (reads on the diaphragm) having a hole and drug loaded member on one side and container comprising dissolution liquid on the other side. The present claims anticipate the copending claims that are later filed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 1-3, 9-14, 17-18, 21, 23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 12/441,842. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the referenced copending applications and would be covered by any patent granted on the copending applications since the referenced copending applications and the instant application are claiming common subject matter as follows: transdermal device comprising holder (reads on the diaphragm) having a hole and drug loaded member on one side and container comprising dissolution liquid on the other side. The present claims anticipate the copending claims that are later filed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-3, 9-14, 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Heiber et el. (US 4,917,676, currently listed on PTO 892), Wakizaka et al. (JP 09-124468 abstract provide by applicant by IDS filed 08/18/2006, and translated full document is currently provided), and Konno et al. (US 4,842,577, currently listed on PTO 892).

Applicant Claims

Applicant s' claim 1 is directed to a patch activated in use comprising: an absorber containing a dry drug and formed of a material capable of absorbing a liquid; a wall material arranged around the absorber and having an adhesive layer on the lower surface thereof; a support arranged on the absorber and the wall material and having an opening at the center; a diaphragm arranged on the support; and a dissolution liquid reservoir arranged on the diaphragm, holding a dissolution liquid dissolving the drug in a space with the diaphragm, and having a protruding portion which breaks the diaphragm by pressure.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Heiber teaches transdermal drug delivery device in pre-activated state for storage stability, manufacture safety and user safety, which is activated by the user before use or after application to the skin (abstract). The device comprises two reservoirs 2 and 3 on top of each other, one contains an activating substance and one contains therapeutic agent and separated by non-permeable membrane 10 that may contain a depth slit to weaken the membrane. Membrane 10 is brustable by pressure (col.3, lines 51-53; col.4, lines 41-65; col.5, lines 8-15; figure 3; claims). Once the activating agent brought into contact with the therapeutic agent, the device is activated and drug flow from the reservoir to the skin begins (col.6, lines 10-17). Activating agent can be solvent or solutions to elute the drug (col.7, lines 7-15).

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

While Heiber teaches transdermal device activated in use by bringing a therapeutic agent and activating agent in contact by rupturing a separating membrane, however, the reference does not explicitly absorbent material containing the therapeutic agent located under the separating membrane as instantly claimed by claim 1.

While Heiber teaches rupturing the membrane separating the activating substance and therapeutic agent to activate the device, and teaches separating membrane weakened by a slit, however the reference does not explicitly teach protrusion to break the membrane, or the separating layer having opening in the center as claimed by claim 1 or the separating membrane is made of aluminum foil as claimed by claim 23.

Wakizaka teaches transdermal device that hardly deteriorates or inactivate medicine during storage, the device comprises blister enclosing and sealing liquid medicine and film sealing the blister and its under surface. The blister comprising protrusion protruding into its interior (abstract, drawings; paragraph 0004). The medicine can be impregnated into absorbent material (paragraph 0017). The device comprises drug transmission layer 2 on the lower surface of the blister and separated from layer 2 by easily destroyed coating membrane 5 of aluminum foil representing the diaphragm layer (paragraphs 0014, 0024). The device has exfoliation layer 4 (release liner) and adhesive to stick the device to the skin (paragraphs 0005, 0009, 0024). The drug transmission layer is drug absorbent material (paragraph 0015). Figures show that the

drug absorbent layers are surrounded by wall that has adhesive on the lower surface. The reference teaches that during use, pressure is applied to the top of the protrusion to destroy the drug coating membrane (paragraphs 0007, 0024).

Konno teaches a transdermal drug device comprising a drug-loaded member (1) provided on the side facing skin of the device, a dissolution liquid-storing container (6) provided on the other side of the device away from the skin, and thin aluminum foil film separating the dissolution liquid-storing container (6) and drug-loaded member (1), wherein the aluminum foil separating membrane comprising liquid passing hole (Figure 4; col.2, line 37 to col.5, line 21). The dissolution liquid passing hole allows for passage of the liquid from the dissolution liquid-storing container (6) into the drug-loaded member (1). As shown in Figure 4, the dissolution liquid-storing container (6) has a recessed portion for storing liquid and a projected portion disposed in the recessed portion, the projected portion being opposed to the dissolution liquid passing hole. The projected portion has a tip for rupturing the thin aluminum foil membrane. The medicament containing layer is absorbent layer impregnated with the drug (col.2, lines 65-68). The device is excellent in skin safety and provides efficient absorption of medicament to the skin (col.1, lines 63-65; col.5, lines 5-8).

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal device activated in use by bringing a

therapeutic agent and activating agent in contact by rupturing a separating membrane as taught by Heiber, and use the structure of the device taught by Wakizaka and Konno that encloses the activating agent in blister comprising protrusion and impregnates the therapeutic agent in an absorbent material wherein the protrusion ruptures the separating membrane upon applying pressure, and use aluminum foil as separating membrane and use a layer that surrounds the drug containing layer secured to the skin by adhesive. One would have been motivated to do so because Wakizaka teaches that such a structure of the device hardly deteriorates or inactivates medicine during storage and aluminum foil is easily destroyed by pressure and because Konno teaches such a device is excellent in skin safety and provides efficient absorption of medicament to the skin. One would reasonably expect formulating transdermal device comprising blister containing an activating agent and protrusion and a therapeutic agent impregnated into absorbent material wherein the blister and the therapeutic agent are separated by easily destroyed aluminum foil layer by virtue of applying pressure to the protrusion, wherein the device is stable during storage and activated in use and has excellent in skin safety and provides efficient absorption of medicament to the skin.

Further, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal device comprising blister containing an activating agent and protrusion and a therapeutic agent impregnated into absorbent material wherein the blister and the therapeutic agent are separated by easily destroyed aluminum foil as taught by combination of Heiber, Wakizaka and Konno, and make a whole in the aluminum foil membrane as taught by Konno. One would have been

motivated to do so because Heiber desired to weaken the membrane separating the two compartments by slit and because Wakizaka desired to rupture the separating membrane, and because Konno teaches that presence of a whole in the separating membrane will provide easy rupturing area to facilitates the passage of material and communication between the two compartments. One would reasonably expect formulating transdermal comprising blister on the side of the device away from the skin containing an activating agent and protrusion, and a therapeutic agent impregnated into absorbent material on the skin side of the device wherein the blister content and the therapeutic agent are separated by easily destroyed aluminum foil having a hole and rupture by applying pressure to the protrusion, wherein the device is stable during storage and easily and effectively activated in use to efficiently and safely deliver the therapeutic agent to the user.

Regarding the limitations of clams 10 and 12, the combination of the references teaches the present structure of the claimed device as a whole, and therefore the device drawn from combination of the references will display and satisfy the claimed equations and relationships as claimed by claims 10 and 12.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

12. Claims 17, 18 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Heiber, Wakizaka and Konno as applied to claims 1-3, 9-14 and 23 above and further in view of Blum et al. (US 7,337,593, currently listed on PRO 892).

Applicant Claims

Applicant s' claims 17 is directed to method of making the reservoir by molding a sheet, and claim 18 recites the thickness of the sheet and claim 21 recites the material of the sheet to include fluorocarbon resin film.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

The combined teachings of Heiber, Wakizaka and Konno are previously discussed in this office action.

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

The references however do not teach method of making the reservoir by molding a sheet as claimed by claim 17, the thickness of the sheet as claimed by claim 18, or the material of the sheet as claimed by claim 21.

Blum teaches blister suitable for packaging pharmaceuticals that has improved excellent moisture and vapor barrier effect including fluorocarbon resin film (title and abstract; col.2, lines 42-48; col.3, lines 1-2; col.8, lines 52-56). Fluorocarbon polymers

are molded to form shaped blister film covering (col.6, lines 7-11). The film having thickness from 1.3-2540 μm to provide readily flexible film (col.8, lines 57-65).

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal comprising blister containing an activating agent and protrusion, and a therapeutic agent impregnated into absorbent material wherein the blister and the therapeutic agent are separated by aluminum foil layer as taught by the combination of Heiber, Wakizaka and Konno, and further form the blister by molding a fluorocarbon resin film having moisture barrier property and having thickness from 1.3-2540 μm as taught by Blum. One would have been motivated to do so because Blum teaches that molded fluorocarbon resin film having thickness from 1.3-2540 μm is excellent moisture and vapor barrier and further readily flexible. One would reasonably expect formulating the wall of the blister of the device taught by the combination of Heiber, Wakizaka and Konno by molding fluorocarbon resin film having thickness from 1.3-2540 wherein the blister wall is excellent barrier and flexible so that suitable for pressing the protrusion inside the blister and mean while protect the enclosed material from moisture and vapor.

Regarding the claimed water vapor permeability as claimed by claim 17, Blum teaches excellent moisture and vapor barrier property of fluorocarbon resin film which provides low permeability which reads on the claimed values.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Communications

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

IG